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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/760,618

01/20/2004

Priscilla Anne Furth

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03/15/2006

LEYDIG, VOIT & MAYER, LTD.
TWO PRUDENTIAL PLAZA, SUITE 4900
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EXAMINER

HAYES, MICHAEL J

ART UNIT

PAPER NUMBER

3767

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/760,618	Applicant(s) FURTH ET AL.	
	Examiner Michael J. Hayes	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 January 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The IDS has been initialed regarding prior art considered. Some non-patent references were not found in the case and have been lined through. Applicant should resubmit these references to have them considered.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the injection port on the side of the injection nozzle as recited in claim 3 must be shown or the feature(s) canceled from the claim(s). Fig. 3 shows the side injection port proximal to the nozzle, not in the side of the nozzle. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 3, 4, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over DIXON (US Patent No. 4,722,728) in view of KWOH (US Patent No. 5,078,140). Dixon discloses an apparatus for jet injections, capable of injecting DNA into cell tissue including an injection nozzle 53, injection tubing 44 connecting nozzle to jet propulsion system, and an end port. Dixon does not disclose attaching the device to a computer-controlled platform for positioning the device for DNA injection or for an endoscope attached to the device. Kwoh teaches attaching devices to a computer-guided platform to position the device for making desired injections and attaching an endoscope for viewing internal sites (3:4-9; 7:63 - 8:11). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Kwoh in the device of Dixon in order to control the location of an injection site.

Re claim 3 it would have been obvious to one of ordinary skill in the art to locate an injection port on the side of the injection nozzle because it is known that the location of the port will impart the direction of the injected fluid in relation to the apparatus. The skilled artisan would find obvious modifications placing the injection port in various locations around the

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nozzle in order to direct the flow of fluid in any desired direction. This would be known to one of ordinary skill as desirable to direct the fluid jet to the desired treatment location.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dixon and Kwoh as applied to claim 1 above, and further in view of OMATA et al. (US Patent No. 4,668,226). Dixon and Kwoh disclose the claimed invention and Kwoh discloses use of its computer movable platform with therapeutic implements including endoscopes, but Dixon and Kwoh do not disclose an endoscopic device running parallel with injection tubing of injector. Omata teaches using an injector with an endoscope running parallel with the injection tubing in order to place the injector in the correct location in a patient (col 3, ll. 22-39). The endoscopic control operating section 12 enables use of the functions of the endoscope. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Omata in the apparatus of Dixon and Kwoh in order to obtain accuracy in locating the target site for medicinal agents in a patient with use of an injector.

Double Patenting

Upon reconsideration of the pending claims, the obviousness double patenting rejection made in the previous office action is withdrawn and a statutory double patenting rejection is made as discussed below.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

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A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-6 are rejected under the statutory type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,361,991. The claims in the '991 patent and the present application claim the same limitations. The claims recite an apparatus comprising an injection nozzle, injection tubing connecting the nozzle to a jet propulsion system affixed to a platform for positioning, and a computer or computer means electrically connected to the platform to provide movement to the platform to position the nozzle on the surface of tissue. The terms computer ('991 patent) and computer means (present application) are interpreted in light of the specification to mean the same structure. Applicant has not provided any definition in the specification to distinguish a computer from a computer means. The functional language recited in the claims does not change the scope of the claims in the present application claims as compared to the corresponding claims in the '991 patent.

The claims recited in the '991 patent and the present application result in the same invention being claimed twice. Upon comparing the claims recited in the present application and the '991 patent it is determined that the claims in the application could not be literally infringed without literally infringing the corresponding claims in the '991 patent. There is no difference in scope between the claims of the present application and the corresponding claims of the '991 patent. The exact wording of the claims varying only in functional language (i.e., for jet injection of DNA into cell tissue and for injection of a polynucleotide into cells; to position a nozzle on the surface of tissue and to position a nozzle on the surface of cells) and recitation of

computer means as compared to computer. The claimed apparatus of the present application and the '991 patent is inherently capable of performing the functional limitations recited and result in the scope of the claims being the same between the claims of the present application and the '991 patent. See MPEP 804(II)(A).

Response to Arguments

Some of Applicant's arguments with respect to claims 1-6 have been considered but are moot in view of the new ground(s) of rejection. Where arguments are still applicable they are addressed below.

Applicant argues that Dixon does not disclose jet injection of DNA as recited in the claims or injection into a cervix. Examiner agrees that Dixon does not specifically disclose jet injection of DNA but maintains the rejection in view of the inherent capability of Dixon to jet inject DNA into a cervix. Due to the shape, size, and arrangement of the jet injector disclosed in Dixon the device is inherently capable of jet injection of DNA into a cervix. Applicant's functional recitation of a particular use of the device does not carry patentable weight. Applicant has not pointed to any structural distinction between the claims and the prior art regarding the functionality of injecting DNA into a cervix. As a jet injector of medicines including a propulsion system, injection tubing guiding the delivery of the injected fluids, and a nozzle, the apparatus disclosed by Dixon is capable of DNA injections into cell tissue and into a cervix.

Applicant argues that Dixon does not disclose a jet propulsion system nor injection nozzle. Applicant is referred to propulsion system shown in figs. 1-3 that forces medicine into cell tissue of a patient and nozzle 53, as discussed in the previous office action. The nozzle is

connected with the jet propulsion system so medicine can be injected into a patient (col. 1, ll. 8-29).

Applicant argues that there is no motivation to combine Kwoh with Dixon. Applicant is referred to Kwoh (col. 8, ll. 23-50). The capability of increased accuracy for injections would motivate the skilled artisan to combine teachings of Kwoh with Dixon. Applicant argues that there is no reasonable expectation that a modification combining Kwoh with Dixon would be successful. Applicant is referred to Kwoh col. 8, ll. 5-11 and the discussion to use the teachings of Kwoh with various medical devices to achieve accuracy in medical procedures.

Applicant argues that claimed elements are missing from the prior and mentions jet injection of DNA and injection tubing (remarks received 12/30/05, pg. 4). The capability of Applicant's apparatus to inject DNA is met by the prior art in disclosing the claimed structural limitations. Regarding injection tubing Applicant is referred to tubing 44, as discussed in previous office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (571) 272-4959. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. The fax number for submitting official papers is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh

11 March 2006

A handwritten signature in black ink, appearing to read "M J Hayes", with a stylized flourish at the end.

MICHAEL J. HAYES
PRIMARY EXAMINER